REMARKS

Claim Objections

Claims 28 and 32 have been amended per the Examiner's suggestions to overcome objections.

Rejections under 35 U.S.C. §103(a)

Claims 28 - 35 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Published Patent Application 2005/0080460 (herein *Wang*) and U.S. Published Patent Application 2005/0203429 (herein *Judy*). These rejections, at least as applied to the claims as amended, are respectfully traversed.

The present invention is directed, *inter alia*, to systems for detecting values representative of ventricular EDV and for detecting the progression of heart failure based on changes in ventricular EDV. Neither *Wang* nor *Judy*, alone or in combination, disclose, teach or suggest this invention.

The Office Action acknowledged that *Wang* does not determine ventricular EDV nor detect the progression of heart failure based on EDV. However, the Office Action asserted that *Wang* describes a microprocessor that may determine a "ventricular tissue fluid content/status value" for "diagnosing a clinically-relevant change in fluid status and/or detecting a progression of heart failure."

Contrary to the Office Action, though, *Wang* makes no mention of detecting the progression of heart failure. Nor does *Wang* describe anything corresponding to a *ventricular* tissue fluid content/status value. *Wang* is instead directed to monitoring changes in thoracic fluid volume to detect pulmonary congestion and "over-dryness" (i.e. over-diuresis) within patients already known to have CHF. In particular, *Wang* is concerned about over-diuresis that can occur within CHF patients during management of their "fluid retention status" via diuretics. [See, e.g., *Wang,* Paragraphs 0002 and 0009.] The fluid status values described therein pertain to pulmonary fluids, not ventricular fluids.

Hence, *Wang* is directed to detecting and managing pulmonary fluid levels, rather than detecting the progression of heart failure or detecting ventricular fluid values. To this end, *Wang* describes systems that exploit an intra-thoracic impedance pathway providing a measurement field that encompasses at least a portion of thoracic volume "occupied by the lungs." [See, e.g., *Wang*, Paragraph 0061.] By employing an impedance pathway that specifically encompasses a portion of thoracic volume occupied by the lungs, the system of *Wang* can thereby detect pulmonary fluid levels for use in detecting possible over-diuresis within the patient. Such an impedance pathway might, of course, additionally and coincidentally encompass ventricular tissues and ventricular blood volumes, but *Wang* does not specifically teach the detection of ventricular fluid volumes or anything corresponding to a "ventricular tissue fluid content/status value."

Moreover, *Wang* indicates that the impedance measurement provided "for purposes of monitoring for pulmonary congestion/edema or dryness" can be performed at a variety of points within the cardiac cycle where "the rate of change in cardiac volume (dV/dt) is near a minimum," such as "the early, isovolumic phase of cardiac systole, late systole near the end of ejection, prior to rapid filling during diastole, or at the end of diastole, prior to the start of systole." The concern is that changes in blood volume of the heart during an impedance measurement intended to detect pulmonary congestion can "add undesirable variation to the impedance measurement." [See, *Wang*, Paragraph 0082.] As such, *Wang* is *not* teaching that impedance measurements should taken at points within the cardiac cycle suitable for detecting ventricular blood volumes to detect or track heart failure. Rather, *Wang* is teaching that impedance measurements should be made so as to *avoid* tracking changes in blood volume of the heart, such that pulmonary congestion can instead be properly detected. Indeed, by characterizing blood volume changes in the heart as having "undesirable" effects on impedance measurements, *Wang* seems to teach away from the present invention, which is specifically directed to exploiting changes in blood volume parameters over time.

Thus, there is simply no teaching or suggestion within *Wang* of any ventricular tissue fluid content/status values or any systems for detecting or tracking the progression of heart failure.

Meanwhile, *Judy* is directed to a non-invasive system for determining LV EDV based, in part, on transthoracic impedance signals measured using an external system. [See, e.g., *Judy*, Paragraph 0001] To this end, the rate of change of an externally-detected transthoracic impedance signal (which is affected by changes in ventricular blood volume as the heart beats) is exploited to calculate LV EDV. [See, e.g., *Judy*, Paragraphs 0028 - 0031]

The Office Action asserted that it would have been obvious to one or ordinary skill in the art to combine the teachings of *Wang* with those of *Judy* to yield the claimed invention. However, since *Judy* is directed to detecting impedance signals that are affected by heart blood volume changes (so as to determine LV EDV), whereas *Wang* is directed to detecting impedance signals that are *not* affected by heart blood volume changes (so as to detect pulmonary congestion and over-diuresis), it would not have been obviously, or even sensible, to combine the teachings of the two references. Indeed, the two references teach away from one another.

In making the rejection based on *Wang* and *Judy*, the Office Action stated that it was considered "conventional and well known in the art to detect the progression of heart failure within a patient by tracking or trending changes in the ventricular EDV of the patient determined or detected over time." Applicant respectfully traverses this reliance on "official notice" and requests that the Examiner cite specific prior art (if any) supporting the assertion that ventricular EDV (as opposed to, e.g., end systolic volume (ESV)) is conventional and well known for use in tracking heart failure. In this regard, MPEP §2144.03 (and applicable case law cited therein) indicates that official notice is not appropriate unless the facts asserted to be well known are capable of instant and unquestionable demonstration as being well known. Assertions of technical facts in the areas of esoteric technology must always be supported by citation. The tracking and trending of the progression of heart failure based on ventricular EDV is sufficiently esoteric to warrant a supporting citation to prior art (if any).

Nevertheless, even assuming (hypothetically) that tracking heart failure based on ventricular EDV is indeed well known, the rejection of Claims 28 - 35 based on a combination of the teachings of *Wang* and *Judy* is still not warranted, since such a combination would not have been obvious to one skilled in the art.

Accordingly, Applicant requests that the rejections of Claims 28 - 35 be withdrawn.

New Claims

New Claims 36 - 53 have been added that depend from Claim 28. These claims generally correspond to the previously cancelled dependent method claims, now re-written as dependent system claims.

More specifically, new Claims 36 - 45 generally correspond to cancelled Claims 4 - 13, respectively. New Claims 46 - 47 generally correspond to cancelled Claims 15 - 16, respectively. New Claims 48 - 52 generally correspond to cancelled Claims 18 - 22, respectively. New Claim 53 generally corresponds to cancelled Claim 25.

The new claims are at least allowable by virtue of their dependency on Claim 28, while providing additional bases for allowance as well. For example, Claim 49 specifies that the claimed EDV detection unit is additionally adapted to detect values representative of passive filling volume. Claim 50 further specifies that the EDV detection unit detects values representative of passive filling volume based, in part, on a detection window derived from a predicted atrial depolarization.

These and other features of the new claims are not taught or suggested by the cited references.

Conclusion

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance.

Respectfully submitted,

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